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ORTHO-MCNEIL PHARMACEUTICAL, INC., now
known as ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.,
and MCKESSON CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CAROLYN GLAZINER, an individual;

Plaintiffs,

v.

ORTHO-MCNEIL PHARMACEUTICAL,
INC., a Delaware Corporation;
MCKESSON CORP. and DOES 1-500,
inclusive,

Defendants.

**DEFENDANTS' ANSWER TO
COMPLAINT; DEMAND FOR JURY
TRIAL**

Defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), and McKesson Corporation ("McKesson") (collectively "Defendants"), by and through counsel, hereby respond to the allegations set forth in Plaintiff's Complaint (the "Complaint"), as follows:

ANSWER TO INTRODUCTION

1. Defendants are without knowledge or information sufficient to form a belief as to Plaintiff's allegations that she used ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 1 of Plaintiff's Complaint.

2. Defendants admit that OMP, now known as OMPJI, manufactured,

1 advertised, promoted, marketed, sold and distributed ORTHO EVRA®. Defendants deny
2 the remaining allegations contained in paragraph 2 of Plaintiff's Complaint.

3 3. Defendants admit that McKesson is a non-exclusive distributor of ORTHO
4 EVRA® and has its principal place of business in San Francisco, California. Defendants
5 deny the remaining allegations contained in paragraph 3 of Plaintiff's Complaint.

6 4. Defendants admit that on the ORTHO EVRA® Web site, it stated that:
7 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents
8 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl
9 estradiol (progestin and estrogen, respectively) through the skin and into the
10 bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for
11 the prevention of pregnancy in November 2001. Defendants further admit that the FDA's
12 publications state what they state. Defendants deny the remaining allegations contained
13 in paragraph 4 of Plaintiff's Complaint.

14 ANSWER TO JURISDICTION AND VENUE

15 5. Paragraph 5 of Plaintiff's Complaint contains legal conclusions to which no
16 response is required.

17 6. Defendants admit that OMP, now known as OMPJI, was a Delaware
18 corporation with its principal place of business in New Jersey, that OMPJI is a
19 Pennsylvania corporation with its principal place of business in New Jersey, and that
20 McKesson is a Delaware corporation with its principal place of business in California.
21 Defendants deny the remaining allegations contained in paragraph 6 of Plaintiff's
22 Complaint.

23 7. Defendants admit that McKesson has its principal place of business in San
24 Francisco, California. Defendants deny the remaining allegations contained in paragraph
25 7 of Plaintiff's Complaint.

26 8. Defendants admit that McKesson has its principal place of business in San
27 Francisco, California. Defendants deny the remaining allegations contained in paragraph
28 8 of Plaintiff's Complaint.

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2 9. Defendants are without knowledge or information sufficient to form a
3 belief as to the allegations contained in paragraph 9 of Plaintiff's Complaint.

4 **ANSWER TO PLAINTIFFS**

5 10. Defendants are without knowledge or information sufficient to form a
6 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed
7 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 10
8 of Plaintiff's Complaint.

9 **ANSWER TO DEFENDANTS**

10 11. Defendants admit that OMP, now known as OMPJI, was a Delaware
11 corporation with its principal place of business in New Jersey and that OMPJI is a
12 Pennsylvania corporation with its principal place of business in New Jersey. Defendants
13 deny the remaining allegations contained in paragraph 11 of Plaintiff's Complaint.

14 12. Defendants admit that OMP, now known as OMPJI, conducts business in
15 California. Defendants deny the remaining allegations contained in paragraph 12 of
16 Plaintiff's Complaint.

17 13. Defendants are without knowledge or information sufficient to form a
18 belief as to the allegations contained in paragraph 13 of Plaintiff's Complaint, and
19 therefore these allegations are denied.

20 14. Defendants are without knowledge or information sufficient to form a
21 belief as to the allegations contained in paragraph 14 of Plaintiff's Complaint, and
22 therefore these allegations are denied.

23 15. Defendants admit that OMP, now known as OMPJI, manufactured,
24 marketed, promoted, sold and distributed ORTHO EVRA®. Defendants deny the
25 remaining allegations contained in paragraph 15 of Plaintiff's Complaint.

26 16. Defendants admit that McKesson is a Delaware corporation with its
27 principal place of business in San Francisco, California. Defendants further admit that
28 McKesson conducts business in California. Defendants deny the remaining allegations
contained in paragraph 16 of Plaintiff's Complaint.

17. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 17 of Plaintiff's Complaint, and therefore these allegations are denied.

18. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 18 of Plaintiff's Complaint, and therefore these allegations are denied.

19. Defendants admit that McKesson is a non-exclusive distributor of ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 19 of Plaintiff's Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 20 of Plaintiff's Complaint.

21. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 21 of Plaintiff's Complaint.

22. To the extent that paragraph 22 of Plaintiff's Complaint alleges improper conduct on the part of Defendants, such allegations are denied.

23. To the extent that paragraph 23 of Plaintiff's Complaint alleges improper conduct on the part of Defendants, such allegations are denied.

ANSWER TO GENERAL ALLEGATIONS

24. OMP, now known as OMPJI, admits that on the OMP Web site, it stated that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in women's health care. Ortho-McNeil offers the broadest range of prescription birth control options..." OMP, now known as OMPJI, further admits that it manufactures and sells ORTHO EVRA®, the first combination transdermal contraceptive patch. Defendants deny the remaining allegations contained in paragraph 24 of Plaintiff's Complaint.

25. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and only once-a-week birth control patch. OMP, now known as OMPJI, further admits that on the ORTHO EVRA® Web site, it stated that: "The transdermal -- or 'through the skin'

1 -- weekly birth control patch prevents pregnancy by delivering continuous levels of the
2 hormones norelgestromin and ethinyl estradiol (progestin and estrogen, respectively)
3 through the skin and into the bloodstream." Defendants deny the remaining allegations
4 contained in paragraph 25 of Plaintiff's Complaint.

5 26. Defendants admit that a New Drug Application ("NDA") was filed for
6 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants
7 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it
8 states. Defendants deny the remaining allegations contained in paragraph 26 of
9 Plaintiff's Complaint.

10 27. Defendants admit that the FDA approved the use of ORTHO EVRA® for
11 the prevention of pregnancy in November 2001. Defendants deny the remaining
12 allegations contained in paragraph 27 of Plaintiff's Complaint.

13 28. Defendants admit that as with all prescription medicine, adverse events are
14 reported to the FDA by a variety of people and entities. Defendants deny the remaining
15 allegations contained in paragraph 28 of Plaintiff's Complaint.

16 29. Defendants admit that the FDA's publications state what they state.
17 Defendants deny the remaining allegations contained in paragraph 29 of Plaintiff's
18 Complaint.

19 30. Defendants admit that the November 2005 package insert for ORTHO
20 EVRA® states what it states. To the extent that paragraph 30 of Plaintiff's Complaint
21 alleges improper conduct on the part of Defendants, such allegations are denied.

22 31. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and
23 only once-a-week birth control patch. Defendants deny the remaining allegations
24 contained in paragraph 31 of Plaintiff's Complaint.

25 32. Defendants deny the allegations contained in paragraph 32 of Plaintiff's
26 Complaint.

27 33. Defendants admit that the package insert for ORTHO EVRA® states what
28 it states. To the extent that paragraph 33 of Plaintiff's Complaint alleges improper

1 conduct on the part of Defendants, such allegations are denied.

2 34. Defendants deny the allegations contained in paragraph 34 of Plaintiff's
3 Complaint.

4 35. Defendants state that they were subject only to those duties imposed by
5 applicable law, and deny the allegations contained in paragraph 35 of Plaintiff's
6 Complaint to the extent they suggest any different or greater duties. Defendants further
7 deny that they failed to abide by any applicable legal duties.

8 36. Defendants deny the allegations contained in paragraph 36 of Plaintiff's
9 Complaint.

10 37. Defendants deny the allegations contained in paragraph 37 of Plaintiff's
11 Complaint.

12 38. Defendants deny the allegations contained in paragraph 38 of Plaintiff's
13 Complaint.

14 39. Defendants deny the allegations contained in paragraph 39 of Plaintiff's
15 Complaint.

16 **ANSWER TO FRAUDULENT CONCEALMENT**

17 40. Defendants deny the allegations contained in paragraph 40 of Plaintiff's
18 Complaint.

19 41. Defendants state that they were subject only to those duties imposed by
20 applicable law, and deny the allegations contained in paragraph 41 of Plaintiff's
21 Complaint to the extent they suggest any different or greater duties. Defendants further
22 deny that they failed to abide by any applicable legal duties, and deny the remaining
23 allegations contained in this paragraph.

24 **ANSWER TO FIRST CAUSE OF ACTION**

25 **NEGLIGENCE**

26 42. Defendants repeat their answers to the allegations of paragraphs 1 through
27 41 of Plaintiff's Complaint as if set forth at length herein.

28 43. Defendants state that they were subject only to those duties imposed by

1 applicable law, and deny the allegations contained in paragraph 43 of the First Cause of
 2 Action of Plaintiff's Complaint to the extent they suggest any different or greater duties.
 3 Defendants further deny that they failed to abide by any applicable legal duties.

4 44. Defendants deny the allegations contained in paragraph 44 of the First
 5 Cause of Action of Plaintiff's Complaint.

6 45. Defendants deny the allegations contained in paragraph 45 of the First
 7 Cause of Action of Plaintiff's Complaint.

8 46. Defendants deny the allegations contained in paragraph 46 of the First
 9 Cause of Action of Plaintiff's Complaint.

10 47. Defendants deny the allegations contained in paragraph 47 of the First
 11 Cause of Action of Plaintiff's Complaint.

12 48. Defendants deny the allegations contained in paragraph 48 of the First
 13 Cause of Action of Plaintiff's Complaint.

14 49. Defendants deny the allegations contained in paragraph 49 of the First
 15 Cause of Action of Plaintiff's Complaint.

16 50. Defendants deny the allegation that ORTHO EVRA® is defective, and
 17 deny the remaining allegations contained in paragraph 50 of the First Cause of Action of
 18 Plaintiff's Complaint.

19 51. Defendants deny the allegations contained in paragraph 51 of the First
 20 Cause of Action of Plaintiff's Complaint.

21 52. Defendants deny the allegations contained in paragraph 52 of the First
 22 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
 23 the unnumbered paragraph following paragraph 52.

24 **ANSWER TO SECOND CAUSE OF ACTION**

25 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

26 53. Defendants repeat their answers to the allegations of paragraphs 1 through
 27 52 of Plaintiff's Complaint as if set forth at length herein.

28 54. Defendants admit that OMP, now known as OMPJI, manufactures and

1 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in
2 paragraph 54 of the Second Cause of Action of Plaintiff's Complaint.

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4 55. Defendants admit that OMP, now known as OMPJI, manufactures and
5 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in
6 paragraph 55 of the Second Cause of Action of Plaintiff's Complaint.

7 56. Defendants deny the allegations contained in paragraph 56 of the Second
8 Cause of Action of Plaintiff's Complaint.

9 57. Defendants deny the allegation that ORTHO EVRA® is defective, and
10 deny the remaining allegations contained in paragraph 57 of the Second Cause of Action
11 of Plaintiff's Complaint.

12 58. Defendants deny the allegation that ORTHO EVRA® is defective, and
13 deny the remaining allegations contained in paragraph 58 of the Second Cause of Action
14 of Plaintiff's Complaint.

15 59. Defendants deny the allegations contained in paragraph 59 of the Second
16 Cause of Action of Plaintiff's Complaint.

17 60. Defendants deny the allegation that ORTHO EVRA® is defective, and
18 deny the remaining allegations contained in paragraph 60 of the Second Cause of Action
19 of Plaintiff's Complaint.

20 61. Defendants deny the allegations contained in paragraph 61 of the Second
21 Cause of Action of Plaintiff's Complaint.

22 62. Defendants deny the allegations contained in paragraph 62 of the Second
23 Cause of Action of Plaintiff's Complaint.

24 63. Defendants deny the allegations contained in paragraph 63 of the Second
25 Cause of Action of Plaintiff's Complaint.

26 64. Defendants deny the allegations contained in paragraph 64 of the Second
27 Cause of Action of Plaintiff's Complaint.

28 65. Defendants deny the allegations contained in paragraph 65 of the Second
Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in

1 the unnumbered paragraph following paragraph 65.

2 **ANSWER TO THIRD CAUSE OF ACTION**

3 **BREACH OF EXPRESS WARRANTY**

4 66. Defendants repeat their answers to the allegations of paragraphs 1 through
5 65 of Plaintiff's Complaint as if set forth at length herein.

6 67. Defendants deny the allegations contained in paragraph 67 of the Third
7 Cause of Action of Plaintiff's Complaint.

8 68. Defendants deny the allegations contained in paragraph 68 of the Third
9 Cause of Action of Plaintiff's Complaint.

10 69. Defendants deny the allegations contained in paragraph 69 of the Third
11 Cause of Action of Plaintiff's Complaint.

12 70. Defendants deny the allegations contained in paragraph 70 of the Third
13 Cause of Action of Plaintiff's Complaint.

14 71. Defendants deny the allegations contained in paragraph 71 of the Third
15 Cause of Action of Plaintiff's Complaint.

16 72. Defendants deny the allegations contained in paragraph 72 of the Third
17 Cause of Action of Plaintiff's Complaint.

18 73. Defendants deny the allegations contained in paragraph 73 of the Third
19 Cause of Action of Plaintiff's Complaint.

20 74. Defendants deny the allegations contained in paragraph 74 of the Third
21 Cause of Action of Plaintiff's Complaint.

22 75. Defendants deny the allegations contained in paragraph 75 of the Third
23 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
24 the unnumbered paragraph following paragraph 75.

25 **ANSWER TO FOURTH CAUSE OF ACTION**

26 **BREACH OF IMPLIED WARRANTY**

27 76. Defendants repeat their answers to the allegations of paragraphs 1 through
28 75 of Plaintiff's Complaint as if set forth at length herein.

77. Defendants admit that OMP, now known as OMPJI, marketed, sold and distributed ORTHO EVRA®, which is used for the prevention of pregnancy. Defendants further admit that McKesson is a non-exclusive distributor of ORTHO EVRA®, and deny that McKesson marketed or sold ORTHO EVRA®. The remainder of paragraph 77 of the Fourth Cause of Action of Plaintiff's Complaint contains a legal conclusion to which no response is required.

78. Paragraph 78 of the Fourth Cause of Action of Plaintiff's Complaint contains legal conclusions to which no response is required.

79. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 79 of the Fourth Cause of Action of Plaintiff's Complaint, and therefore these allegations are denied.

80. Defendants deny the allegations contained in paragraph 80 of the Fourth Cause of Action of Plaintiff's Complaint.

81. Defendants deny the allegations contained in paragraph 81 of the Fourth Cause of Action of Plaintiff's Complaint.

82. Defendants deny the allegations contained in paragraph 82 of the Fourth Cause of Action of Plaintiff's Complaint.

83. Defendants deny the allegations contained in paragraph 83 of the Fourth Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 83.

ANSWER TO FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

84. Defendants repeat their answers to the allegations of paragraphs 1 through 83 of Plaintiff's Complaint as if set forth at length herein.

85. Defendants admit that OMP, now known as OMPJI, manufactures, markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in this paragraph to the extent they suggest any different or greater duties.

1 Defendants further deny that they failed to abide by any applicable legal duties, and deny
2 the remaining allegations contained in paragraph 85 of the Fifth Cause of Action of
3 Plaintiff's Complaint.

4 86. Defendants deny the allegations contained in paragraph 86 of the Fifth
5 Cause of Action of Plaintiff's Complaint.

6 87. Defendants deny the allegations contained in paragraph 87 of the Fifth
7 Cause of Action of Plaintiff's Complaint.

8 88. Defendants deny the allegations contained in paragraph 88 of the Fifth
9 Cause of Action of Plaintiff's Complaint.

10 89. Defendants deny the allegations contained in paragraph 89 of the Fifth
11 Cause of Action of Plaintiff's Complaint.

12 90. Defendants deny the allegations contained in paragraph 90 of the Fifth
13 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
14 the unnumbered paragraph following paragraph 90.

15 **ANSWER TO SIXTH CAUSE OF ACTION**

16 **FRAUD**

17 91. Defendants repeat their answers to the allegations of paragraphs 1 through
18 90 of Plaintiff's Complaint as if set forth at length herein.

19 92. Defendants admit that OMP, now known as OMPJI, manufactures,
20 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were
21 subject only to those duties imposed by applicable law, and deny the allegations
22 contained in this paragraph to the extent they suggest any different or greater duties.
23 Defendants further deny that they failed to abide by any applicable legal duties, and deny
24 the remaining allegations contained in paragraph 92 of the Sixth Cause of Action of
25 Plaintiff's Complaint.

26 93. Defendants deny the allegations contained in paragraph 93 of the Sixth
27 Cause of Action of Plaintiff's Complaint.

28 94. Defendants deny the allegations contained in paragraph 94 of the Sixth

1 Cause of Action of Plaintiff's Complaint.

2 95. Defendants deny the allegations contained in paragraph 95 of the Sixth
3 Cause of Action of Plaintiff's Complaint.

4 96. Defendants deny the allegations contained in paragraph 96 of the Sixth
5 Cause of Action of Plaintiff's Complaint.

6 97. Defendants deny the allegations contained in paragraph 97 of the Sixth
7 Cause of Action of Plaintiff's Complaint.

8 98. Defendants deny the allegations contained in paragraph 98 of the Sixth
9 Cause of Action of Plaintiff's Complaint.

10 99. Defendants deny the allegations contained in paragraph 99 of the Sixth
11 Cause of Action of Plaintiff's Complaint.

12 100. Defendants are without knowledge or information sufficient to form a
13 belief as to Plaintiffs' states of mind. Defendants deny the remaining allegations
14 contained in paragraph 100 of the Sixth Cause of Action of Plaintiff's Complaint.

15 101. Defendants deny the allegations contained in paragraph 101 of the Sixth
16 Cause of Action of Plaintiff's Complaint.

17 102. Defendants deny the allegations contained in paragraph 102 of the Sixth
18 Cause of Action of Plaintiff's Complaint.

19 103. Defendants deny the allegations contained in paragraph 103 of the Sixth
20 Cause of Action of Plaintiff's Complaint.

21 104. Defendants deny the allegations contained in paragraph 104 of the Sixth
22 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
23 the unnumbered paragraph following paragraph 104.

24 **FIRST AFFIRMATIVE DEFENSE**

25 Plaintiff's Complaint fails to state a claim against Defendants upon which relief
26 may be granted.
27

SECOND AFFIRMATIVE DEFENSE

Venue is improper in this court.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs are fraudulently joined and/or misjoined, and the court should sever Plaintiffs' claims and/or enter other appropriate orders to avoid prejudice, unfairness, hardship, delay, and undue expense and to promote convenience and expedience.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent certain Plaintiffs have asserted duplicative claims in one or more other actions pending against some or all of the same defendants.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose and/or by the equitable doctrines of laches and estoppel.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrines of informed consent, release and waiver.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the alleged damages, if any are proven, were not proximately caused by any act or omission of any of the Defendants.

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of a responsible, superseding, and/or intervening cause.

NINTH AFFIRMATIVE DEFENSE

Defendants state that if Plaintiffs have suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were due to an allergic,

1 idiosyncratic or idiopathic reaction to the product at issue in this case, or by an
 2 unforeseeable illness, unavoidable accident or preexisting condition, without any
 3 negligence and culpable conduct by Defendants.

4 **TENTH AFFIRMATIVE DEFENSE**

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 6 Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts
 7 (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration,
 8 omission or fault of one or more persons or entities over whom Defendants exercised no
 9 control and for whom Defendants are not legally responsible, including, without
 10 limitation, Plaintiffs.

11 **ELEVENTH AFFIRMATIVE DEFENSE**

12 Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and
 13 damages, if any.

14 **TWELFTH AFFIRMATIVE DEFENSE**

15 Plaintiffs' claims are barred by the "state of the art" and "state of scientific
 16 knowledge" defenses.

17 **THIRTEENTH AFFIRMATIVE DEFENSE**

18 Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

19 **FOURTEENTH AFFIRMATIVE DEFENSE**

20
 21 The product at issue in this case falls under the auspices of the Food, Drug and
 22 Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,
 23 and therefore, Federal law preempts Plaintiffs' claims. *See*, 21 U.S.C. §301 *et. seq.* *See*
 24 *also*, 71 Fed. Reg. 3922 (January 24, 2006).

25 **FIFTEENTH AFFIRMATIVE DEFENSE**

26 Defendants did not make to Plaintiffs nor did they breach any express or implied
 27 warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely
 28 on any theory of breach of warranty, such claims are barred by applicable law, and for

1 lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs'
2 representatives, to give timely notice to Defendants of any alleged breach of warranty.
3 Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as
4 to any breach of warranty claim all affirmative defenses under the Uniform Commercial
5 Code existing and which may arise in the future, as enacted in the State of California, and
6 any other state whose law is deemed to apply in this case.

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8 **SIXTEENTH AFFIRMATIVE DEFENSE**

9 Plaintiffs' claims are barred by comments j and k to Section 402A of the
10 Restatement (Second) of Torts.

11 **SEVENTEENTH AFFIRMATIVE DEFENSE**

12 Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of
13 the Restatement (Third) of Torts: Products Liability.

14 **EIGHTEENTH AFFIRMATIVE DEFENSE**

15 Plaintiffs' product liability claims are barred because the benefits of the relevant
16 product outweighed its risks.

17 **NINETEENTH AFFIRMATIVE DEFENSE**

18 Plaintiffs' claims are barred in whole or part because the product at issue was at all
19 times properly prepared, packaged, and distributed, and was not defective or
20 unreasonably dangerous.

21 **TWENTIETH AFFIRMATIVE DEFENSE**

22 Any imposition of punitive damages in this case against Defendants is barred to
23 the extent that the manner in which such punitive damages are calculated violates the
24 Constitution of the United States or the Constitution of the State of California.

25 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

26 Any award of punitive damages in this case against Defendants is barred to the
27 extent that the amount of such an award violates the Constitution of the United States or
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1 the Constitution of the State of California.

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3 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

4 Plaintiffs have failed to plead fraud with specificity.

5 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

6 Defendants are entitled to a setoff for all amounts paid, payable by or available
7 from collateral sources.

8 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

9 The Complaint fails to state a cause of action against Defendants because there is
10 no private right of action under the applicable federal law. To the extent Plaintiffs'
11 claims are based on alleged misrepresentations or omissions made to FDA, such claims
12 are barred pursuant to *Buckman v. Plaintiffs' Legal Community*, 531 U.S. 341 (2001).

13 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

14 Plaintiffs knowingly and voluntarily assumed any and all risks associated with the
15 use of the product at issue, barring in whole or in part the damages Plaintiffs seek to
16 recover.

17 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

18 In the event Defendants, or any of them, are held liable to Plaintiffs, or any of
19 them, which liability is expressly denied, or a settlement of judgment against Defendants,
20 or any of them, is reached, Defendants request an apportionment of fault be made as
21 permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle*
22 *Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of
23 indemnification and contribution be entered against all other persons and entities in
24 accordance with that apportionment of fault.
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TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The amount of any award on behalf of Plaintiffs, or any of them, for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 ("Proposition 51").

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TWENTY- EIGHTH AFFIRMATIVE DEFENSE

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

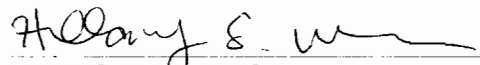
WHEREFORE, having fully answered, Defendants specifically controvert Plaintiffs' Prayer for Relief including Paragraphs (1)-(6).

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JURY DEMAND

Defendants hereby demand a trial by jury of all the facts and issues in this case pursuant to Federal Rule of Civil Procedure 38(b).

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Dated: April 16, 2008

DRINKER BIDDLE & REATH


CHARLES F. PREUSS
HILLARY S. WEINER
Attorneys for Defendants
ORTHO-MCNEIL PHARMACEUTICAL,
INC., now known as ORTHO-MCNEIL-
JANSSEN PHARMACEUTICALS, INC.,
and MCKESSON CORPORATION